UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION _____ **THIS DOCUMENT RELATES TO WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PEGGY PENCE, PH.D.

Plaintiffs' brief does not seriously refute the well-settled legal principles cited in Ethicon's brief as a basis to exclude Dr. Pence's testimony.[1] Ethicon files this reply to address two discreet issues: (1) Dr. Pence's failure to account for what physicians already know, and (2) Dr. Pence's reliance on GHTF Guidelines for her opinion that Ethicon should have warned of the frequency and severity of the risks.

ARGUMENT

A. Dr. Pence's testimony should be excluded because she failed to consider physicians' preexisting knowledge of the risks.

Plaintiffs' response to Ethicon's argument is wrong on the facts and the law.

On the facts, Plaintiffs claim that Ethicon's citation of Dr. Pence's admission that she does not take into account what physicians know is an "out-of-context snippet of testimony [that] misstates the factual record and is misleading to the Court." [Doc. 2949, p. 6]. Not so.

[1] Some of Plaintiffs' brief is nonresponsive to the arguments raised here. For instance, Plaintiffs claim that "Ethicon challenges Dr. Pence's characterization of the incidents detailed in her Report as being 'representative' of the rationales applied by Ethicon in the other thirty-two instances." [Doc. 2949, p. 10]. This argument was not raised in Ethicon's motion in these cases. Plaintiffs appear to have copied this portion of their brief from their response brief in the *Lewis* case, where this argument was at issue. *See Lewis v. Ethicon*, No. 2:12-cv-04301, Doc. 166, p. 29 (S.D. W. Va. Dec. 27, 2013).

Ethicon's argument is fully supported by Dr. Pence's explanation of her methodology. And Plaintiffs are simply wrong when they say "[t]he record shows that Dr. Pence has considered what physicians know about the risks of the product and does not consider that knowledge irrelevant in forming her opinions regarding the adequacy of the Ethicon IFUs." [Doc. 2949, p. 6].

For example, Plaintiffs claim that "Dr. Pence has also considered the medical literature, which supports her opinion that doctors performing procedures with mesh many not know the complications even with their own patients." [Doc. 2949, p. 6] (citing Pence Dep. 185:11-186:5). But in this portion of the deposition, Dr. Pence only cited a study that, according to her, showed that physicians may not know about a patient's complications because she may have gone to another doctor to treat her complications. This study only supports that a physician may not know his or own personal complication rate, not that they would not know the risks of mesh overall. And it has no bearing on whether Dr. Pence took physicians' knowledge into account in her methodology.

Further, Plaintiffs claim that "Dr. Pence has considered that physicians may learn from adverse events in the medical literature but has stated that even where physicians know of a risk, they may not know the incidence or percentage of that risk." [Doc. 2949, p. 6]. But in her deposition, Dr. Pence was clear that with respect to frequency and severity, the physicians' knowledge was *irrelevant* to her opinion about what should be in the IFU:

> Q. Are you assuming that the 30,000 or so surgeons, and it might be less, that are actually trained in the surgical treatment of stress urinary incontinence do not know frequency data of adverse events?
>
> Q. Are you making that assumption?
>
> A. I'm not making an assumption***. I'm stating that it's really irrelevant as to what goes in the labeling.*** There are standards. There are regulations, and there's a global standard for what's supposed to go into the labeling.

Pence 3/24/16 Dep. at 161:24-162:12 [Doc. 2759-8, pp. 42-43] (emphasis added) (counsel objection omitted). Dr. Pence went on to reiterate the point later in her deposition, as noted in Ethicon's brief, when she said that information about physician's pre-existing knowledge of the risks is "not relevant to my opinion as to what should go into the IFU." *Id.* at 193:13-14. [Doc. 2759-8, p. 50]. And critically—a fact entirely ignored by Plaintiffs in their response—*nowhere* in her Rule 26 Reports does Dr. Pence give any indication whatsoever that she has taken physicians' knowledge into account in her methodology.

Plaintiffs are also wrong on the law. In their response, they erroneously claim that "Defendants cite to no applicable standard which would allow a device manufacturer to omit risk information from a medical device IFU based on what physicians already know" and that "[t]here is nothing in any regulation, guidance, or industry standard that allows a device manufacturer to omit a warning or adverse event based on the fact that doctors may already know about the risk." [Doc. 2949, p. 5]. This is not true.

As cited in Ethicon's brief, the FDA device regulations explicitly provide that information commonly known to the device's users need not be included in a device's labeling, and the Blue Book Guidance indicates frequency data may be omitted if well-known. [Doc. 2760, p. 5] (citing, e.g., 21 C.F.R. §801.109(c)).

But irrespective of the regulations, Dr. Pence's opinions do not comport with the law to be applied by the jury in these cases. This is an additional reason to exclude Dr. Pence's testimony because expert testimony which fails to rest on the proper legal standard is inadmissible. *See* Memorandum in Support of Defendant Johnson & Johnson and Ethicon Inc's Motion to Exclude Peggy Pence Ph.D. [Doc. 2760, p. 6 & n.2]. Plaintiffs cite nothing to rebut the authorities cited in Ethicon's brief on this point.

Dr. Pence has expressly admitted that she does not know what knowledge physicians had and, in her analysis of the warnings, she plainly did not take that knowledge into account. Her testimony rests on the erroneous assumption that there is no such exception to the duty to warn. Simply put, her opinions do not "fit" the law of the case, and so they should be excluded in their entirety.

B. Dr. Pence's opinion that Ethicon had a duty to warn of the frequency and severity of risks is unreliable.

In support of their argument that Ethicon should have warned of the frequency or severity of the risks, Plaintiffs point to the GHTF document "Essential Principles of Safety and Performance of Medical Devices, November 2, 2012." [Doc. 2949, p. 8]. However, this document is not on point.

Though it is true that this particular GHTF document defines "risk" as the "combination of the probability of occurrence of harm and the severity of that harm," the purpose of this document was not to provide guidance on device labeling. [Doc. 2949-3, p. 9]. Rather, that guidance document was intended to describe "fundamental design and manufacturing requirements." [Doc. 2949-3, p. 6]. As this Court has observed, the GHTF guidance that is actually applicable to labeling, the GHTF's Label and Instructions for Use for Medical Devices [Doc. 2759-9], contains no such requirement. *See Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *26 (S.D. W. Va. Apr. 28, 2015).

Further, the GHTF document cited by Plaintiff also states that "[u]sers should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, ***taking account of their training and knowledge***." [Doc. 2949-3, p. 18] (emphasis added). As described above and in Ethicon's motion, Dr. Pence has no basis for knowing the training and knowledge of the products' users and erroneously believes

that information irrelevant when it comes to what should be in an IFU.

Dr. Pence's opinion is unreliable and should be excluded.

CONCLUSION

For these reasons, and those stated in Ethicon's motion and memorandum in support, Ethicon respectfully requests that Dr. Pence's testimony be excluded in its entirety.[2]

Respectfully submitted,

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[2] Ethicon notes that in their response brief [Doc. 2949, p. 4], Plaintiffs state that "Defendants have moved to exclude Dr. Pence's testimony in the entirety, but have also offered nine areas of testimony which they request be excluded." [Doc. 2949, p. 4]. To clarify, the sections of Ethicon's brief address each of the different categories of Dr. Pence's opinions offered in her expert reports. *See* Doc. 2760, p. 1 (explaining the subjects of Dr. Pence's testimony and how they correspond to the sections of the memorandum). If the Court excludes each of these areas of testimony, then Dr. Pence's testimony should be excluded in the entirety in all cases.

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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